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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/543,084	01/26/2006	Julien Meissonnier	03762.015900	1166

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	PAPER NUMBER
1615	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/543,084	MEISSONNIER ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *1-9 and 15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/15/08;1/30/09;2/10/09;10/30/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response to Restriction/Election Requirement filed 10/30/09 and the Information Disclosure Statements (IDS) filed 12/15/08, 01/30/09, 02/10/09 and 10/30/09 is acknowledged.

Applicant's election of Group II (claims 10-14) and Election of Species of: (1) lipophilic vehicle – (h) silicone oil, simethicones and (2) coating – (a) celluloses – ethylcellulose, hydroxyethylcellulose, hydroxymethylcellulose, hydroxypropylmethylcellulose acetate in the reply filed on 30 October 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Also note that the Election of species was required for Group I only and not Groups II and III.

Claims 1-9 and 15 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/30/09.

Claims 1-15 are pending in this action. Claims 1-9 and 15 have been withdrawn. Claims 10-14 have been examined in this action. Claims 10-14 are rejected.

* * * * *

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 12/15/08, 01/30/09, 02/10/09 and 10/30/09 is acknowledged. The submission is in compliance with the provisions of 37

CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites, "wherein said lipophilic vehicle has a solubilizing power for the active substance of less than 1.5 times the active substance concentration for which a taste is detected in water". It is unclear as to what the limitation "for which a taste is detected in water" is intended to mean. The language presented is relative and the metes and bounds of the limitation cannot be properly ascertained. If Applicant is referring to masking of bitter taste of drug, then the claim should be presented to read so. Clarification is requested.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hutchinson *et al.* (hereinafter "Hutchinson") (U.S. Pat. No. 5,817,323).

Hutchinson ('323) teaches soft gelatin capsule shell compositions. The compositions comprise as the shell material, gelatin (18-30%), plasticizer (30 to 45%), such as glycerol, and a further component compatible with the gelatin, such as unbleached starch acetate, another starch derivative, starch itself or mixtures thereof, whereby the further component is normally no more than 12% (see column 1, lines 1-59); (col. 2, lines 17-30). The chewability of the compositions can be enhanced by inclusion of an oil (i.e., coconut oil). Oil disperses within the shell structure as microscopic droplets (col. 2, lines 31-46). Suitable hydrophobic solvent/carrier media

components are discussed at column 5, lines 32-42). Hutchinson teaches that where the encapsulated contents include particles in suspension, the particles may be separately coated, typically with suitably sweetened or flavored coatings. Such a coating can serve as either or both of a taste-masking agent and a stabilizer in the suspension (col. 5, lines 61-67).

With respect to the amounts/ranges of the ingredients in claim 13 (i.e., gelatin, plasticizer, etc.), the amounts and ranges disclosed by Ebert meet and/or overlap with the amounts/ranges as instantly claimed. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Moreover, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

While the references do not explicitly teach that the lipophilic vehicle has a "solubilizing power for the active substance of less than 1.5 times the active substance concentration for which a taste is detected in water", the Hutchinson reference, nonetheless teaches active substances embedded within a fill composition that is comprised of the same components, namely, hydrophobic (lipophilic) components and recognizes that their drug particles can be coated for taste-masking purposes and stabilization of the suspensions. The solubility characteristics or solubilization power would be expected to be similar if not the same based on incorporation of the same ingredients under similar conditions, absent a showing of evidence to the contrary.

Moreover, it would be well within the purview of the skilled artisan at the time the invention was made to adjust the solubilizing power or solubility characteristics by routine or manipulative experimentation during the capsule formulation process.

The instant invention when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, given the teachings of Hutchinson.

* * * * *

Claims 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas *et al.* (hereinafter "Douglas") (U.S. Pat. No. 5,635,200) in view of Hutchinson *et al.* (hereinafter "Hutchinson") (U.S. Pat. No. 5,817,323).

Douglas ('200) teaches chewable soft gelatin capsules comprising (a) a dispersion of lipid coated particles of ranitidine or an acceptable salt thereof in a non-aqueous vehicle; (b) particles comprising ranitidine or an acceptable salt thereof incorporated into a core and coated with a lipid coating; c) lipid coated particles in the form of ranitidine which is poorly soluble in water (see Abstract); (col. 2, lines 8-24).

. The bitter taste may be masked by coating the drug substance with a suitable lipid (col. 1, lines 50-67). The pharmaceutical composition can be in the form of chewable soft gelatin capsules (col. 6, lines 39-45).

Douglas does not teach the shell components (gelatin, plasticizer, starch) in the amounts claimed.

Hutchinson ('323) teaches soft gelatin capsule shell compositions. The compositions comprise gelatin (18-30%), plasticizer (30 to 45%), such as glycerol, and a further component compatible with the gelatin, such as unbleached starch acetate, another starch derivative, starch itself or mixtures thereof, whereby the further component is normally no more than 12% (see column 1, lines 1-59); (col. 2, lines 17-30). The chewability of the compositions can be enhanced by inclusion of an oil (i.e., coconut oil) and plasticizers. Oil disperses within the shell structure as microscopic droplets (col. 2, lines 17-46). Suitable hydrophobic solvent/carrier media components are discussed at column 5, lines 32-42). Hutchinson teaches that where the encapsulated contents include particles in suspension, the particles may be separately coated, typically with suitably sweetened or flavored coatings. Such a coating can serve as either or both of a taste-masking agent and a stabilizer in the suspension (col. 5, lines 61-67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the shell components (gelatin, plasticizer, starch) in the amounts as claimed by Hutchinson within the capsules of Douglas. One would do so with a reasonable expectation of success because Hutchinson explicitly teaches that the chewability of the capsules can be enhanced by inclusion of an oily component and plasticizers and teaches that their drug particles may be separately coated, typically with suitably sweetened or flavored coatings, in order to provide for taste-masking effects as well as to impart stability to the capsule composition. Based on the modification of Douglas by Hutchinson, the expected result would yield an improved soft chewable capsule having enhanced stability and taste-masking effects.

With respect to the amounts/ranges of the ingredients in claim 13 (i.e., gelatin, plasticizer, etc.), the amounts and ranges disclosed by Hutchinson meet and/or overlap with the

amounts/ranges as instantly claimed. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Moreover, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

While the references do not explicitly teach that the lipophilic vehicle has a "solubilizing power for the active substance of less than 1.5 times the active substance concentration for which a taste is detected in water", the Hutchinson reference, nonetheless teaches active substances embedded within a fill composition that is comprised of the same components, namely, hydrophobic (lipophilic) components and recognizes that their drug particles can be coated for taste-masking purposes and stabilization of the suspensions. The solubility characteristics or solubilization power would be expected to be similar if not the same based on incorporation of the same ingredients under similar conditions, absent a showing of evidence to the contrary. Moreover, it would be well within the purview of the skilled artisan at the time the invention was made to adjust the solubilizing power or solubility characteristics by routine or manipulative experimentation during the capsule formulation process.

Hence, the instant invention when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, given the combined teachings of Douglas and Hutchinson.

* * * * *

Claims 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebert *et al.* (hereinafter "Ebert") (U.S. Pat. No. 4,532,126) in view of Hutchinson *et al.* (hereinafter "Hutchinson") (U.S. Pat. No. 5,817,323).

Ebert ('126) teaches a chewable, filled, one-piece soft elastic gelatin (SEG) capsule and method for its manufacture, wherein the SEG capsule is formed from a formulation of gelatin (about 10-90 % by wt.), water (about 5-40 % by wt.), a plasticizer (e.g., sorbitol) and a masticatory substance and taste modifiers (about 0-10 % by wt.). The gelatin is present in the shell and incorporates a fill material contained within the shell, whereby the fill material may be selected from a variety of materials including candy, confectionaries, antacids, cough and cold preparations, sore throat remedies, antiseptics and dental preparations, such as fluorides, breath fresheners and the like. Conventional SEG capsules comprising gelatin have a bloom value of about 150-200, although this value may be varied (see Abstract); (column 1, line 60 – col. 2, line 68).

In manufacturing the SEG capsules, a molten gel mass is prepared with a dispersion of a molten masticatory substance therein. A suitable fill material is also prepared. The gelatin formulation containing the masticatory substance dispersed therein is formed as a shell around the fill material. The capsules are dried until the desired chewing characteristics are attained (Abstract); (col. 2, lines 46-53).

Suitable taste modifiers or flavorings added to the fill composition, the gelatin composition or in both simultaneously and can be selected from cherry syrup, citric acid,

dextrose, essential oil (i.e., clove, lemon, orange, peppermint, spearmint), ethyl vanillin, glucose, honey, mannitol, methyl salicylate, raspberry syrup, saccharin, saccharin sodium, sorbitol, sucrose, wild cherry syrup and mixtures thereof (col. 4, lines 13-26). The gelatin capsules are formed into any desired shape, color and size (col. 4, lines 35-42).

With respect to the amounts/ranges of the ingredients in claim 13 (i.e., gelatin, plasticizer, etc.), the amounts and ranges disclosed by Ebert meet and/or overlap with the amounts/ranges as instantly claimed. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Moreover, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Ebert does not teach coated crystals or granules of active agent in a lipophilic vehicle.

Hutchinson ('323) teaches soft gelatin capsule shell compositions. The compositions comprise gelatin (18-30%), plasticizer (30 to 45%), such as glycerol, and a further component compatible with the gelatin, such as unbleached starch acetate, another starch derivative, starch itself or mixtures thereof, whereby the further component is normally no more than 12% (see column 1, lines 1-59); (col. 2, lines 17-30). The chewability of the compositions can be enhanced by inclusion of an oil (i.e., coconut oil). Oil disperses within the shell structure as microscopic droplets (col. 2, lines 31-46). Suitable hydrophobic solvent/carrier media

components are discussed at column 5, lines 32-42). Hutchinson teaches that where the encapsulated contents include particles in suspension, the particles may be separately coated, typically with suitably sweetened or flavored coatings. Such a coating can serve as either or both of a taste-masking agent and a stabilizer in the suspension (col. 5, lines 61-67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the coated drug particles that are provided in a hydrophobic (lipophilic) vehicle as taught by Hutchinson within the capsules of Ebert. One would do so with a reasonable expectation of success because Hutchinson explicitly teaches that the chewability of the capsules can be enhanced by inclusion of an oily component and teaches that their drug particles may be separately coated, typically with suitably sweetened or flavored coatings, in order to provide for taste-masking effects as well as to impart stability to the capsule composition. In addition, Ebert discloses a gelatin capsule comprising gelatin, water and taste-modifiers or flavorings, whereby the capsule comprises a fill material containing various ingredients, including medicaments, candies and confectionaries. The reference recognizes the importance of avoiding unpleasant taste upon breakage of the capsule shell in order to release the fill components. The avoidance of unpleasant taste is particularly significant for fill components comprising medicaments or therapeutic agents, which generally are known to exhibit poor taste. Based on the modification of Ebert by Hutchinson, the expected result would yield an improved soft chewable capsule having enhanced stability and taste-masking effects.

While the references do not explicitly teach that the lipophilic vehicle has a "solubilizing power for the active substance of less than 1.5 times the active substance concentration for which a taste is detected in water", the Hutchinson reference, nonetheless teaches active substances

embedded within a fill composition that is comprised of the same components, namely, hydrophobic (lipophilic) components and recognizes that their drug particles can be coated for taste-masking purposes and stabilization of the suspensions. The solubility characteristics or solubilization power would be expected to be similar if not the same based on incorporation of the same ingredients under similar conditions, absent a showing of evidence to the contrary. Moreover, it would be well within the purview of the skilled artisan at the time the invention was made to adjust the solubilizing power or solubility characteristics by routine or manipulative experimentation during the capsule formulation process.

Hence, the instant invention when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, given the combined teachings of Ebert and Hutchinson.

* * * * *

Conclusion

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday-Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

February 16, 2010